

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kathryn E. Uhrich	Examiner:	Blessing M. Fubara
Serial No.:	10/712,416	Group Art Unit:	1618
Filed:	November 10, 2003	Docket:	01435.010US3
Title:	THERAPEUTIC AZO-COMPOUNDS FOR DRUG DELIVERY		

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicant respectfully requests that this Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to MPEP 609, Applicant requests that a copy of the Form 1449, initialed as being considered by the Examiner, be returned to the Applicant with the next official communication.

Copies of "Foreign Patent Documents" and "Other Documents" listed on the Form 1449 are not included as these documents were either submitted to or cited by the Office in Serial No. 09/917,595, which application was filed on July 27, 2001, or Serial No. 10/647,701, which application was filed on August 25, 2003.

Pursuant to 37 C.F.R. § 1.97, no fee or statement is required with the Information Disclosure Statement. However, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 503503 in order to have this Information Disclosure Statement considered. The Examiner is invited to contact the Applicant's Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,
Kathryn E. Uhrich et al.,
By their Representatives,
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952 876-4094

Date

September 13, 2006

By

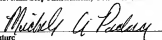

Peter L. Valen
Reg. No. 44,894

CERTIFICATE: I hereby certify that this correspondence is being transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment; Commissioner for Patents; P.O. Box 1450, Alexandria, VA 22313-1450, on this 13th day of September, 2006.

Name

Michelle Padua

Signature



Substitute for Form 1449A/PTO and/or 1449B/PTO
**INFORMATION DISCLOSURE
 STATEMENT BY APPLICANT**
 (Use as many sheets as necessary)

Complete if Known

Application Number	10/712,416
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Examiner Name	Blessing M. Fubara

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US PATENT DOCUMENTS

Examiner Initials *	US Document Number	Publication Date	Name of Patentee/Applicant of Document
	4,062,855	12/13/1977	Allan, G. G. et al.
	4,126,445	11/21/1978	Allan, G. G. et al.
	4,190,716	02/26/1980	Parkinson et al.
	4,298,595	11/03/1981	Parkinson, T. et al.
	4,684,620	08/04/1987	Hruby et al.
	4,757,128	07/12/1988	Domb, A. J. et al.
	4,792,598	12/20/1988	Ziegast, G.
	4,857,311	08/15/1989	Domb, A. J. et al.
	4,868,274	09/19/1989	Gupta, B. et al.
	4,886,870	12/12/1989	D'Amore, P. et al.
	4,886,176	12/19/1989	Langer, R. S. et al.
	4,891,225	01/02/1990	Langer, R. S. et al.
	4,906,474	03/06/1990	Langer, R. S. et al.
	4,997,904	03/05/1991	Domb, A. J.
	4,999,417	03/12/1991	Domb, A. J.
	5,082,925	01/21/1992	Shalaby, S.W. et al.
	5,175,235	12/29/1992	Domb, A. J. et al.
	5,259,968	11/09/1993	Emert, J. et al.
	5,264,540	11/23/1993	Cooper, K. et al.
	5,498,729	03/12/1996	Domb, A. J.
	5,514,764	05/07/1996	Fretchet, J.M.L. et al.
	5,518,730	05/21/1996	Fulz, R.C.
	5,545,409	08/13/1996	Laurencin, C.T. et al.
	5,629,009	05/13/1997	Laurencin, C.T. et al.
	5,889,028	03/30/1999	Sandborn, W. et al.
	5,902,599	05/11/1999	Anseth, K.S. et al.
	5,942,252	08/24/1999	Tice, T. et al.
	6,071,530	06/06/2000	Polson, A. et al.
	6,153,212	11/28/2000	Mao, H. et al.
	6,602,915	08/05/2003	Uhrich
	2004/0044125	03/04/2004	Uhrich

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document Number (include country code)	Publication Date	Translation (Abstract Only or Full Translation, if applicable)
	WO-91/09831	07/11/1991	
	WO-97/39738	10/30/1997	
	WO-98/36013	08/20/1998	
	WO-99/12990	03/18/1999	
	WO-99/29885	06/17/1999	
	WO-01/28492	04/26/2001	
	WO-02/09767	02/07/2002	

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* Examiner Initial if document considered; whether or not the date is in accordance with MPEP 609. Draw line through date if not considered. Include copy of this form with next communication to Applicant

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**INFORMATION DISCLOSURE
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FOREIGN PATENT DOCUMENTS

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	WO-02/09768	02/07/2002	
	WO-02/09769	02/07/2002	
	DE-288311	03/28/1991	
	DE-288387	03/28/1991	
	EP-0246341	11/25/1987	
	NL-9000237	08/16/1991	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner or Initials*	Include last name of the first author (in CAPITAL letters), "Title of the Article", Title of the Source (book, magazine, journal, serial, symposium, catalog, etc.), Volume-Number, page(s) and (date).
	Anastasiou, T.J., "Novel Polyanhydrides with Enhanced Thermal and Solubility Properties", <i>Macromolecules</i> , 33 (17), (2000), pp. 6217-6221.
	Anastasiou, T.J., "Novel, Degradable Polyanhydrides", 25th Annual Meeting Transactions of the Society for Biomaterials, Abstract, (1999), p. 79.
	Anastasiou, T.J., "Synthesis of Novel, Degradable Polyanhydrides Containing Para-Aminosalicylic Acid as Drug Delivery Devices for Tuberculosis Treatment", <i>Polymer Preprints</i> , 41 (2), (Aug. 2000), pp. 1366-1367.
	Attawia, M.A., "Biocompatibility Testing of Poly(anhydride-co-imides) Containing Pyromellitylimidoalanine", The 21st Annual Meeting of the Society for Biomaterials, Abstract (1994), p. 222.
	Attawia, M.A., "Regional drug delivery with radiation for the treatment of Ewing's sarcoma--In vitro development of a taxol release system", <i>Journal of Controlled Release</i> , 71, (2001), pp. 193-202.
	Beaton, M.L., "Synthesis of a novel poly(anhydride-ester)", The Rutgers Scholar-- An Electronic Bulletin of Undergraduate Research, 3, www.rutgersscholar.rutgers.edu/volume03/beatuhri/beatuhri.html , (2001), 7 pgs.
	Bedell, C., "Processing and Hydrolytic Degradation of Aromatic, Ortho-Substituted Polyanhydrides", <i>Journal of Applied Polymer Science</i> , 80, (2001), pp. 32-38.
	Brown, J.P., et al., "A Polymeric Drug for Treatment of Inflammatory Bowel Disease", <i>J. Med. Chem.</i> , 26, (1983), 1300-1307.
	Campo, C.J., "Polyanhydrides: the effects of ring substitution changes on polymer properties", <i>Polymer Bulletin</i> , 42, (1999), pp. 61-68.
	Chafi, N., "Dosage Form with Salicylic Acid Attached to the Polyanhydride Polymer Dispersed in an Eudragit Matrix", <i>International Journal of Pharmaceutics</i> , 52, (1989), pp. 203-211.

EXAMINER

DATE CONSIDERED

Substitute Information Disclosure Statement Form (PFD-1449)

*Examiner: Initials if document considered, whether or not the citation is in accordance with MPEP § 802. Draw line through citation if not considered. Include only of this form with final communication to Applicant.

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OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examin or Initials*	Include last name of the first author (in CAPITAL letters), "Title of the Article", Title of the Source (book, magazine, journal, serial, symposium, catalog, etc.), Volume-Number, page(s) and (date).
	Chatterjee, R., et al., "Mechanism for the Increase in Solubility of Deoxyhemoglobin S Due to Cross-Linking the beta Chains between Lysine-82beta1 and Lysine-82beta2", Biochemistry, 21, (1982),5901-5909.
	Conix, A., "Aromatic Polyanhydrides, a New Class of High Melting Fiber-Forming Polymers", Journal of Polymer Science, XXIX, (1958),pp. 343-353.
	Conix, A., "New High-Melting Fibre-Forming Polymers", Die Makromolekulare Chemie, XXIV, (1957),pp. 76-78.
	Conix, A., "Poly[1,3-bis(p-carboxyphenoxy)-Propane anhydride]", Macromolecular Synthesis, 2, (1996),pp.95-99.
	Conix, A., et al., "New High-Melting Fibre-Forming Polymers", Die Makromolekulare Chemie, XXIV, (1957), 76-78.
	Davaran, S., et al., "Release of 5-amino Salicylic Acid from Acrylic Type Polymeric Prodrugs Designed for Colon-specific Drug Delivery", Journal of Controlled Release, 58, (1999),279-287.
	Domb, A.J., "Synthesis and Characterization of Biodegradable Aromatic Anhydride Copolymers", Macromolecules, 25, (1992),pp. 12-17.
	Dukovic, G., "Novel degradable poly(anhydride-esters) for controlled drug release", The Rutgers Scholar--An Electronic Bulletin of Undergraduate Research, 1, http://rutgersscholar.rutgers.edu/colume01/uhriduko/uhriduko.html , (1999),10 pgs.
	Erdmann et al. "Polymeric Prodrugs: Novel Polymers with bioactive components", in Tailored Polymeric Materials for Controlled Delivery Systems, McCulloch et al. edited, ACS Symposium Series 709, 1998, pp. 83-91.
	Erdman, L., et al., "Polymer Prodrugs with Pharmaceutically Active Degradation Products", Polymer Preprints, 38 (2), (1997),pp. 570-571.
	Erdmann, L., "Degradable poly(anhydride ester) implants: effects of localized salicylic acid release on bone", Biomaterials, 21, (2000),pp. 2507-2512.
	Erdmann, L., "Polymeric Prodrugs: Novel Polymers for Delivery of Salicylic Acid", Annals of Biomedical Engineering, 26 (Suppl. 1), Abstract No. PB.26, Annual Fall Meeting, (1998),p. S-124.
	Erdmann, L., "Polymeric Salicylic Acid: In Vitro and In Vivo Degradation", Polymer Preprints, 39 (2), (1998),p. 224-225.
	Erdmann, L., "Synthesis and Characterization of a Polymeric Prodrug", Proceedings of the American Chemical Society Division of Polymeric Materials: Science and Engineering, 78, Abstract of Spring Meeting, Dallas, TX, (1998),p. 194.

EXAMINER

DATE CONSIDERED

Exhibit to Information Disclosure Statement Form (PTO-4449)

* Examinee: Initial if document considered; whether or not the date is in accordance with MPEP 609. Draw line through date(s) if not considered. Retain copy of this form with root communication to Applicant.

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OTHER DOCUMENTS – NON PATENT LITERATURE DOCUMENTS

Examin or Initials*	include last name of the first author (in CAPITAL letters), "Title of the Article", <u>Title of the Source</u> (book, magazine, journal, serial, symposium, catalog, etc.), <u>Volume-Number</u> , page(s) and (date).
	Erdmann, L., "Synthesis and degradation characteristics of salicylic acid-derived poly(anhydride-esters)", <i>Biomaterials</i> , 21, (2000), pp. 1941-1946.
	Giammona, G., "Polymeric Prodrugs alpha beta poly-hydroxyethyl-d1-aspartamide as macromolecular carrier for some non-steroidal anti-inflammatory agents", Abstract for Database BIOSIS Online, Bioscience Information Service, Philadelphia, PA, Original Publication from the International Journal of Pharmaceutics (Amsterdam), (1989), 1 pg.
	Gouin, S., et al., "New Polyanhydrides Made From a Bile Acid Dimer and Sebacic Acid: Synthesis, Characterization, and Degradation", <i>Macromolecules</i> , 33, (2000), pp. 5379-5383.
	Ibim, S.M., "Poly(anhydride-co-imides): In Vivo Biocompatibility in a rat model", <i>Biomaterials</i> , 19, (1998), pp. 941-951.
	Ibim, S., "Controlled Release Based on Poly(anhydride-co-imides)", <i>Proc. Intern. Symp. Control. Rel. Bioact. Mater.</i> , 22, (1995), 2 pgs.
	Ibim, S.E., "Preliminary In Vivo Report on the Osteocompatibility of Poly(anhydride-co-imides) evaluated in a Tibial Model", <i>App. Biomater.</i> , 43 (4), (1998), pp. 374-379.
	Jiang, H.L., et al., "Synthesis, Characterization and In Vitro Degradation of a New Family of Alternate Poly(ester-anhydrides) Based on Aliphatic and Aromatic Diacids", <i>Biomaterials</i> , 22, (2001), 211-218.
	Kompella et al. "Means to enhance penetration, delivery systems for penetration enhancement of peptide and protein drugs: design considerations," <i>Adv. Drug Del. Reviews</i> , 8, 115-162; abstract (1992).
	Kompella et al. "Delivery systems for penetration enhancement of peptide and protein drugs: design considerations," <i>Adv. Drug Del. Reviews</i> , 46, 211-245 (2001).
	Krogh-Jespersen, E., "Synthesis of a Novel Aromatic Polyanhydride Containing Aminosalicilic Acid", <i>Polymer Preprints</i> , 41 (1), (2000), pp. 1048-1049.
	Langer, R., "New Methods of Drug Delivery", <i>Science</i> , 249, (Sep. 1990), pp. 1527-1533.
	Laurencin, C.T., "The Biocompatibility of Poly(anhydride-co-imides): High Strength Polymers for Controlled Drug Delivery", <i>Proc. 24th Int'l Symp. Control. Rel. Bioact. Mater.</i> , (1997), pp. 973-974.
	Laurencin, C.T., "The Bone Biocompatibility of Poly(anhydride-co-imides)—A new generation degradable Polymer for Orthopedic Applications", 41st Annual Meeting of the Orthopedic Research Society, Orlando, FL, (1995), pp. 143-224.
	Laurencin, C.T., "The Controlled Delivery of Radiosensitizers: Taxol Treatment for Ewing Sarcoma", <i>Proc. of the 25th Int'l Symp. Control. Rel. Bioact. Mater.</i> , (1998), pp. 236-237.
	Macedo, B., et al., "The in vivo Response to a Bioactive Biodegradable Polymer", <i>Journal of Dental Research</i> , 78, Abstract No. 2827, (1999), 459.

EXAMINER

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Substitute Information Disclosure Statement Form (PTO-5445)

* Examiner: Initial if document considered, whether or not the citation is in accordance with MPEP 608. Do not use through citation if not considered. Include only of this item with oral communication to Applicant.

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OTHER DOCUMENTS – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Include last name of the first author (in CAPITAL letters), "Title of the Article", Title of the Source (book, magazine, journal, serial, symposium, catalog, etc.), Volume-Number, page(s) and (date).
	Macedo, B., "the In Vivo Response to Bioactive Polyanhydride Monofilament", Journal of Dental Research, 79 (Abstract No. 3872), (2000), p. 627.
	Pinther, P., "Synthesis of Polyanhydrides Containing Ester Groups", Makromol. Chem., Rapid Commun., 11, (1990), pp. 403-408.
	Schacht, E., et al., "Polymers for Colon Specific Drug Delivery", Journal of Controlled Release, 39, (1996), 327-338.
	Seidel, J.O., "Erosion of Poly(anhydride-co-imides): A Preliminary Mechanistic Study", J. Appl. Polym. Sci., 62(8), (1996), pp. 1277-1283.
	Shen, E., "Morphological Characterization of Erodible Polymer Carriers for Drug Release", Proc. 26th Int'l Symp. Control. Rel. Bioact. Mater., (1999), pp. 717-718.
	Uhrich, K.E., "Chemical Changes during in vivo degradation of poly(anhydride-imide) matrices", Biomaterials, 19, (1998), pp. 2045-2050.
	Uhrich, K.E., "Degradation of poly(anhydride-co-imides): Novel Polymers for Orthopedic Applications", Mat. Res. Soc. Symp. Proc., 394, (1995), pp. 41-46.
	Uhrich, K.E., "In Vitro Degradation Characteristics of Poly(anhydride-imides) Containing Pyromellitylimidoalanine", J. Appl. Polymer Sci., Part A, Polym. Chem., 34 (7), (1996), pp. 1261-1269.
	Uhrich, K.E., "In Vitro Degradation Characteristics of Poly(anhydride-imides) Containing trimellitylimidoglycine", J. Appl. Polymer Sci., 63 (11), (1997), pp. 1401-1411.
	Uhrich, K.E., "Poly(anhydride-ester) Degradation: Mechanical Changes and Correlation to Antibiotic Release", American Chemical Society, Abstracts of Papers, Part 2, Abstract No. 121, 221st ACS National Meeting, San Diego, CA, (2001), 1 pg.
	Uhrich, K.E., "Synthesis and Characterization of Degradable poly(anhydride-co-imides)", Macromolecules, 28 (7), (1995), pp. 2184-2193.
	Uhrich, K.E., "Synthesis and Characterization of poly(anhydride-co-imides): Solution Polycondensation of Biodegradable Polymers Derived from Amino Acids", Proc. of the American Chemical Society, Division of Polymeric Materials: Science and Engineering, 70, Spring Meeting, San Diego, CA, (1994), pp. 239-240.
	Uhrich, K.E., "Synthesis of Aminosalicylate-based polyanhydride Prodrugs: Esters, Amides, and Azos", American Chemical Society, Abstracts of Papers, Part 2, Abstract No. 407, 222nd ACS National Meeting, Chicago, IL, (2001), 1 pg.

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Substitute Information Disclosure Statement Form (PTO-1449)

* Examiner Initial if document considered, whether or not the citation is in accordance with MPEP § 809. Draw line through citation if not considered. Include copy of this form with next communication to Applicant